

Claims

What is claimed is:

1. A composition comprising fenofibrate and at least one pharmaceutical excipient, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50%
5 in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.
2. The composition according to claim 1, wherein the at least one pharmaceutical excipient is at least one binder, at least one filler, at least one pigment, at least one disintegrating
10 agent, at least one lubricant, at least one wetting agent, at least one buffer, or a mixture of two or more thereof.
3. The composition according to claim 1, wherein the at least one pharmaceutical excipient is at least one disintegrating agent.
4. The composition according to claim 1, wherein the at least one pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch,
15 colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.
- 20 5. The composition of claim 1, wherein the fenofibrate is present in an amount of 5 to 50% by weight.
6. The composition of claim 1, wherein the fenofibrate is present in an amount of 20 to 45% by weight.
7. The composition of claim 1 in the form of a tablet.
- 25 8. The composition of claim 1 in the form of a capsule.
9. A composition comprising fenofibrate, at least one inert carrier and at least one pharmaceutical excipient, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating

blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

10. The composition according to claim 9, wherein the at least one pharmaceutical excipient is at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, or a mixture of two or more thereof.

11. The composition according to claim 9, wherein the at least one pharmaceutical excipient is at least one disintegrating agent.

12. The composition according to claim 9, wherein the at least one pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.

15 13. The composition of claim 9, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

14. The composition of claim 9, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

15. The composition of claim 9 in the form of a tablet.

20 16. The composition of claim 9 in the form of a capsule.

17. An orally administrable tablet comprising fenofibrate and at least one pharmaceutical excipient, wherein the tablet has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80 or a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

25 18. The tablet according to claim 17, wherein the at least one pharmaceutical excipient is at least one binder, at least one filler, at least one pigment, at least one disintegrating

agent, at least one lubricant, at least one wetting agent, at least one buffer, or a mixture of two or more thereof.

19. The tablet according to claim 17, wherein the at least one pharmaceutical excipient is at least one disintegrating agent.

5 20. The tablet according to claim 17, wherein the at least one pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch, hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a
10 mixture of two or more thereof.

21. The tablet according to claim 17, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

22. The tablet according to claim 17, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

15 23. An orally administrable capsule comprising fenofibrate and at least one pharmaceutical excipient, wherein the capsule has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80 or a dissolution medium constituted by
20 water with 0.025 M sodium lauryl sulfate.

24. The capsule according to claim 23, wherein the at least one pharmaceutical excipient is at least one binder, at least one filler, at least one pigment, at least one disintegrating agent, at least one lubricant, at least one wetting agent, at least one buffer, or a mixture of two or more thereof.

25 25. The capsule according to claim 23, wherein the at least one pharmaceutical excipient is at least one disintegrating agent.

26. The capsule according to claim 23, wherein the at least one pharmaceutical excipient is selected from the group consisting of microcrystalline cellulose, lactose, starch, colloidal silica, talc, glycerol esters, sodium stearyl fumarate, titanium dioxide, magnesium
30 stearate, stearic acid, cross-linked polyvinyl pyrrolidone, carboxymethyl starch,

hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, and a mixture of two or more thereof.

27. The capsule according to claim 23, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

5 28. The capsule according to claim 23, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

10 29. A composition comprising fenofibrate and at least one disintegrating agent, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

30. The composition according to claim 29, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.

15 31. The composition of claim 29, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

32. The composition of claim 29, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

33. The composition of claim 29 in the form of a tablet.

20 34. The composition of claim 29 in the form of a capsule.

35. A composition comprising fenofibrate, at least one inert carrier and at least one disintegrating agent, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

25 36. The composition according to claim 35, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.

37. The composition of claim 35, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

38. The composition of claim 35, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

5 39. The composition of claim 35 in the form of a tablet.

40. The composition of claim 35 in the form of a capsule.

10 41. An orally administrable tablet comprising fenofibrate and at least one disintegrating agent, wherein the tablet has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80 or a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

15 42. The tablet according to claim 41, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.

43. The tablet according to claim 41, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

44. The tablet according to claim 41, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

20 45. An orally administrable capsule comprising fenofibrate and at least one disintegrating agent, wherein the capsule has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80 or a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

25 46. The capsule according to claim 45, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.

47. The capsule according to claim 45, wherein the fenofibrate is present in an amount of 5 to 50% by weight.

48. The capsule according to claim 45, wherein the fenofibrate is present in an amount of 20 to 45% by weight.

5 49. The composition according to claim 1, wherein the fenofibrate is in a non-reagglomerated form.

50. The composition according to claim 9, wherein the fenofibrate is in a non-reagglomerated form.

10 51. The tablet according to claim 17, wherein the fenofibrate is in a non-reagglomerated form.

52. The capsule according to claim 23, wherein the fenofibrate is in a non-reagglomerated form.

53. The composition according to claim 29, wherein the fenofibrate is in a non-reagglomerated form.

15 54. The composition according to claim 35, wherein the fenofibrate is in a non-reagglomerated form.

55. The tablet according to claim 41, wherein the fenofibrate is in a non-reagglomerated form.

20 56. The capsule according to claim 45, wherein the fenofibrate is in a non-reagglomerated form.